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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/040,518	03/17/1998	COSTAS N. KARATZAS	06632/011001	1912

7590                    01/29/2002

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EXAMINER

BAKER, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No. <b>09/040,518</b>	Applicant(s) <b>Karatzas et al.</b>
Examiner <b>Anne-Marie Baker, Ph.D.</b>	Art Unit <b>1632</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 17, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## THE PERIOD FOR REPLY [check only a) or b)]

- a)  The period for reply expires 6 months from the mailing date of the final rejection.
- b)  In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_ . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3.  The proposed amendment(s) will not be entered because:
- (a)  they raise new issues that would require further consideration and/or search. (See NOTE below);
  - (b)  they raise the issue of new matter. (See NOTE below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See Part A on attached sheet.

4.  Applicant's reply has overcome the following rejection(s):  
If entered, the proposed amendment to Claim 5 would overcome the rejection of Claim 5 under 35 U.S.C. 112, second paragraph.
5.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Part B on attached sheet.
7.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8.  For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
 Claim(s) allowed: NONE  
 Claim(s) objected to: NONE  
 Claim(s) rejected: 1-5 and 7-21
9.  The proposed drawing correction filed on \_\_\_\_\_ a)  has b)  has not been approved by the Examiner.
10.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
11.  Other:

*Anne-Marie Baker*  
**ANNE-MARIE BAKER**  
**PATENT EXAMINER**

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### **Advisory Action**

At page 2 of Applicants' response, Applicants state that the Examiner agreed, in a telephone discussion, to enter the present amendment and to fully consider the arguments and the accompanying declaration. However, this is not the case. The Examiner only agreed to an interview. The Examiner has never seen this amendment before and would not and did not agree to enter an after final amendment sight unseen. Furthermore, the Examiner did not agree to consider a declaration after final. On July 24, 2001, Paul Clark contacted the Examiner and stated that he was preparing a preliminary amendment and a declaration for this case. The Examiner informed him that she had already sent out a final rejection on July 18th. The Attorney requested a personal interview for September 11th or sometime thereafter and indicated that he would call back to set up a specific time. The Examiner agreed to meet with the Attorney for a personal interview. The Attorney called back on September 17th and left a message requesting an interview for September 27th. The Examiner left a message for the Attorney on September 18th suggesting an alternate time. The Attorney next left a message for the Examiner on January 17, 2002 requesting a fax number for submission of an after final response and an interview. The Examiner subsequently left a message for the Attorney on January 18th providing the fax number and informing him that she would be on vacation January 27th through February 3. The Examiner suggested setting up an interview after February 4th.

With regard to the Karatzas Declaration filed January 17, 2002, the Examiner would like to point out that declarations submitted under 37 CFR 1.132 are not considered timely when filed after a final rejection, unless submitted in response to a new ground of rejection made in the final rejection. In this case, no new ground of rejection was made in the final rejection. See MPEP 716.01.

### **Part A.**

The proposed amendments would require a new ground of rejection under 35 U.S.C. 112, second paragraph. Claim 13 has been amended to remove the phrase "to produce an animal comprising biofilament expressing and secreting cells" in step (b). However, step (c) still recites "said biofilament

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expressing and secreting cells.” Thus, the phrase “said biofilament expressing and secreting cells” now lacks antecedent basis. Furthermore, step (a) of Claim 13 has been amended so that it no longer recites “a nucleic acid molecule that expresses and causes secretion of said biofilament from a milk-producing or urine-producing cell,” but now broadly recites “a nucleic acid molecule encoding a biofilament.” However, step (b) now recites producing “an animal comprising milk-producing or urine-producing cells that express and secrete said biofilament.” This claim language is confusing given that the nucleic acid molecule used to transform the embryonal cell is no longer limited to a construct that has the elements necessary for expression in and secretion from milk-producing or urine-producing cells.

**Part B.**

With the exception of the arguments directed to the contents of the Karatzas Declaration, Applicants’ arguments are not unlike those filed previously. The claims stand rejected under 35 U.S.C. 112, first and second paragraphs for reasons of record. Additionally, Claim 2 stands rejected under 35 U.S.C. 101 for reasons of record.

With regard to the evidence presented in the Karatzas Declaration, the Examiner recommends timely filing the declaration for consideration in a continuation application.